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Title: Laboratory Equipment		
Revision: 3	Replaces: 12/11/92	Effective: 9/13/96

1. Purpose:

To ensure adequate and proper equipment for the conduct of USDA/AMS-Pesticide Data Program (PDP) analytical work and storage/archiving of samples.

2. Scope:

This standard operating procedure (SOP) shall be followed by all analytical laboratories which are conducting residue studies for PDP, including support laboratories conducting stability or other types of studies which may impact the program.

3. Outline of Procedure:

- 5.1 Equipment Design
- 5.2 Equipment Maintenance and Calibration

4. References:

USDA/AMS-PDP SOP No. INST-1, <u>Maintenance Procedures and Documentation</u>, current version

USDA/AMS-PDP SOP No. INST-2, Instrument Calibration, current version

USDA/AMS-PDP SOP No. INST-3, Instrument SOPs and Manual, curent version

USDA/AMS-PDP SOP No. INST-4, <u>Injection Sequence</u>, current version

USDA/AMS-PDP SOP No. INST-5, MS Tuning and Operational Guide, current version.

EPA/OPP, U.S. EPA/OCM Meeting, Minutes, May 21, 1992

U.S. EPA SOP No. GLP-02, <u>Determining Compliance of Audited Studies with GLP Standards Requirements</u>, pg. 11, October 1, 1990

U.S. EPA, Equipment Design, 40 CFR part 160.61, August 17, 1989

U.S. EPA, <u>Maintenance and Calibration of Equipment</u>, 40 CFR part 160.63, August 17, 1989

5. Specific Procedure

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5.1 Equipment Design

Equipment used in the generation, measurement, or assessment of data for PDP and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the study protocol and SOPs and shall be suitably located for operation, inspection, cleaning, and maintenance.

- 5.2 Maintenance and calibration of equipment.
 - a. Refer to SOP PDP-INST-1 through PDP-INST-5 for detailed information.
 - b. Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated, and/or standardized.
 - c. The written SOPs shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written SOPs shall designate the person responsible for the performance of each operation.
 - d. Written records shall be maintained of all inspection, maintenance, testing, calibration, and/or standardization operations. These records, containing the dates or the operations, shall describe whether the maintenance operations were routine and followed the written SOPs. Written records shall be kept of nonroutine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect.
 - e. Data packages shall reflect which specific instruments and equipment were used to generate, measure, or assess the data.

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f. Data on the calibration and/or standardization of applicable (e.g., gas chromatographs (GCs), mass selective detectors (MSDs), etc.) equipment and instruments is to be included in the raw data packages. Calibration and/or standardization data for balances, refrigerators, and other peripheral equipment does not need to be included in the raw data package.

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9/11/96

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